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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,166	01/17/2006	Arne Hermansen	Q-87648	9199
23373 7590 01/10/2008 SUGHRUE MION, PLLC		EXAMINER		
2100 PENNSYLVANIA AVENUE, N.W.			PANDE, SUCHIRA	
	SUITE 800 WASHINGTON, DC 20037		ART UNIT	PAPER NUMBER
			1637	
			MAIL DATE	DELIVERY MODE
			01/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
2	10/533,166	HERMANSEN ET AL.			
Office Action Summary	Examiner	Art Unit			
	Suchira Pande	1637			
The MAILING DATE of this communication app		orrespondence address			
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on 06 De	ecember 2007.				
,	·				
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) Claim(s) 1,4,6,7,10-14,17 and 22 is/are pending in the application.					
4a) Of the above claim(s) <u>1,4 and 6</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed. 6)⊠ Claim(s) <u>7, 10-14,17 and 22</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or	r election requirement.				
Application Papers					
9) The specification is objected to by the Examine	r.				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
,					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
	·				
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summary				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P				
Paper No(s)/Mail Date <u>11/13/06, 12/06/07</u> .	6) Other:				

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group II invention (product) claims 7, 10-14, 17 and 22 in the reply filed on December 6, 2007 is acknowledged. Applicant has amended claims 1, 4, 6, 7, 10-14, 17 and 22; cancelled claims 2-3, 5, 8-9, 15-16 and 18-21.

Claims 1, 4 and 6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method claims, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 6, 2007.

Applicant has also elected Pythium species for examination and indicated that primers of formula Ia-Xb fall within this species. Applicant has elected primers of SEQ ID No 17 and 18 (IXa-IXb) for examination. Since applicant has indicated that elected primers of SEQ ID No 17 and 18 are complementary to primers of SEQ ID NO 7 and 8 (IVa and IVb), for a complete comprehensive compact prosecution, Examiner is including a search for SEQ ID No 7 and 8 along with the above two elected SEQ IDs.

Claims 7, 10-14, 17 and 22 are currently pending and will be examined in this action to the extent they read upon the elected primers of SEQ ID NOs 17 and 18 and their complement SEQ ID NO 7 and 8 respectively.

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Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 11/13/2006 and 12/06/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claims 7, 10-14, 17 and 22 are objected to because of the following informalities: All of the above claims refer to formulae identified by Roman numerals. Since all these formulae actually refer to oligonucleotide primers that are longer than 10 nucleotides, they must be identified by their corresponding SEQ ID numbers in the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 7, 10-14, 17 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 7, 10-14, 17 and 22 the use of phrase ---- "which hybridizes to"--- in the claim language while claiming primers of the instant claims makes the claims indefinite. The specification does not provide guidance regarding the hybridization conditions (stringency etc.) to one of ordinary skill hence it is not possible to unambiguously determine the meets and bounds of the claimed invention. Absent guidance re hybridization conditions it is not possible to determine which oligos will hybridize and which will not. Is there a certain percent identity below which the claimed oligos will not hybridize or they have to be 100% homologous to hybridize?

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Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 7. Claims 7, 10, 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al. (2000). Mycol. Res. 104 (11):1333-1341 in view of Buck et al. (1999) Biotechniques 27: 528-536.

Regarding claims 7, 10 and 13-14, Matsumoto, C., Kageyama, K. and Suga, H. teach

sequence of a region that comprises sequences that have 100% sequence homology to the claimed primers of SEQ ID NO 17 and its complement SEQ ID No 7 as well as SEQ ID No 18 and its complement SEQ ID No 8. See the alignment provided below.

```
Application/Control Number:
                                                           Page 5
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Art Unit: 1637
AB108008
                                     907 bp
                                               DNA
                                                       linear
                                                                PLN 15-APR-
LOCUS
            AB108008
2003
DEFINITION Pythium sylvaticum genes for ITS1, 5.8S rRNA, ITS2, complete
            sequence, strain: Py77.
ACCESSION
            AB108008
            AB108008.1 GI:29837164
VERSION
KEYWORDS
SOURCE
            Pythium sylvaticum
  ORGANISM Pythium sylvaticum
            Eukaryota; stramenopiles; Oomycetes; Pythiales; Pythiaceae;
            Pythium.
REFERENCE
           Matsumoto, C., Kageyama, K. and Suga, H.
  AUTHORS
            Intraspecific DNA polymorphisms of Pythium irregulare
  TITLE
            Mycological Research 104, 1333-1341 (2000)
  JOURNAL
            2 (bases 1 to 907)
REFERENCE
            Kageyama, K. and Matsumoto, C.
  AUTHORS
  TITLE ·
            Direct Submission
            Submitted (11-APR-2003) Koji Kageyama, River Basin Research
  JOURNAL
Center,
            Gifu University; 1-1 Yanagido, Gifu, Gifu 501-1193, Japan
            (E-mail:kageyama@cc.gifu-u.ac.jp, Tel:81-58-293-2063,
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                                                   0;
                                                       Indels
                                                                 0;
                                                                     Gaps
0;
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                                              (SEQ ID NO 17= IXa)
Qу
              514 CGCTGTGGTTGGTATATTTGT 534
Db
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RESULT 9 AB108008/c

LOCUS AB108008 907 bp DNA linear PLN 15-APR-

2003

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Application/Control Number: Page 6
10/533,166
Art Unit: 1637

DEFINITION Pythium sylvaticum genes for ITS1, 5.8S rRNA, ITS2, consequence, strain: Py77.
```

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DEFINITION Pythium sylvaticum genes for ITS1, 5.8S rRNA, ITS2, complete
            AB108008
ACCESSION
            AB108008.1 GI:29837164
VERSION
KEYWORDS
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SOURCE
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            Eukaryota; stramenopiles; Oomycetes; Pythiales; Pythiaceae;
            Pythium.
REFERENCE
            1
            Matsumoto, C., Kageyama, K. and Suga, H.
  AUTHORS
            Intraspecific DNA polymorphisms of Pythium irregulare
  TITLE
            Mycological Research 104, 1333-1341 (2000)
  JOURNAL
            2 (bases 1 to 907)
REFERENCE
  AUTHORS
           Kageyama, K. and Matsumoto, C.
            Direct Submission
  TITLE
            Submitted (11-APR-2003) Koji Kageyama, River Basin Research
  JOURNAL
Center,
            Gifu University; 1-1 Yanagido, Gifu, Gifu 501-1193, Japan
            (E-mail:kageyama@cc.gifu-u.ac.jp, Tel:81-58-293-2063,
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0;

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RESULT 6
AB108008/c
LOCUS AB108008 907 bp DNA linear PLN 15-APR-
2003
DEFINITION Pythium sylvaticum genes for ITS1, 5.8S rRNA, ITS2, complete
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sequence, strain: Py77.
ACCESSION
            AB108008
            AB108008.1 GI:29837164
VERSION
KEYWORDS
            Pythium sylvaticum
SOURCE
  ORGANISM Pythium sylvaticum
            Eukaryota; stramenopiles; Oomycetes; Pythiales; Pythiaceae;
            Pythium.
REFERENCE
            1
  AUTHORS
            Matsumoto, C., Kageyama, K. and Suga, H.
            Intraspecific DNA polymorphisms of Pythium irregulare
  TITLE
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            2 (bases 1 to 907)
REFERENCE
            Kageyama, K. and Matsumoto, C.
  AUTHORS
            Direct Submission
  TITLE
            Submitted (11-APR-2003) Koji Kageyama, River Basin Research
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            (E-mail:kageyama@cc.gifu-u.ac.jp, Tel:81-58-293-2063,
            Fax:81-58-293-2062)
FEATURES
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     rRNA
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                                                                 0;
                                                                     Gaps
                               0; Mismatches
                                                   0;
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Qу
              Db
          843 GCCAATTGCACAAGTACAAA 824
RESULT 6
AB108008
                                     907 bp
                                               DNA
                                                       linear
                                                                PLN 15-APR-
LOCUS
            AB108008
2003
DEFINITION Pythium sylvaticum genes for ITS1, 5.8S rRNA, ITS2, complete
            sequence, strain: Py77.
            AB108008
ACCESSION
```

AB108008.1 GI:29837164

VERSION

Application/Control Number:

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10/533,166 Art Unit: 1637

```
KEYWORDS
SOURCE
           Pythium sylvaticum
  ORGANISM Pythium sylvaticum
           Eukaryota; stramenopiles; Oomycetes; Pythiales; Pythiaceae;
           Pythium.
REFERENCE
           1
 AUTHORS
           Matsumoto, C., Kageyama, K. and Suga, H.
           Intraspecific DNA polymorphisms of Pythium irregulare
  TITLE
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  JOURNAL
REFERENCE
           2 (bases 1 to 907)
           Kageyama, K. and Matsumoto, C.
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           Direct Submission
  TITLE
           Submitted (11-APR-2003) Koji Kageyama, River Basin Research
  JOURNAL
Center,
           Gifu University; 1-1 Yanagido, Gifu, Gifu 501-1193, Japan
            (E-mail:kageyama@cc.gifu-u.ac.jp, Tel:81-58-293-2063,
           Fax:81-58-293-2062)
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FEATURES
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     misc RNA
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                                                  0; Indels
                                                               0; Gaps
0;
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                                           (SEQ ID No 8 = IVb)
Qу
              824 TTTGTACTTGTGCAATTGGC 843
Db
```

Note the sequences of all the above primers 21 (SEQ ID No 17 and 7) and 20 (SEQ ID NO 18 and 8) bases long.

As indicated above Matsumoto et al. teach the region of Pythium species that encompasses the regions that are claimed as primers of the instant invention.

Regarding claim 7, Matsumoto et al. teach an 18- to 24-mer oligonucleotide primer (SEQ ID No 17 = IXa and SEQ ID No 18 =IXb) which hybridizes to an

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oligonucleotide sequence (SEQ ID NO 7 = IVa and SEQ ID No 8 = IVb) selected from the group consisting of formulae IVa, IVb, IXa, IXb.

Regarding claim 10, Matsumoto et al. teach the primer as claimed in claim 7, wherein said primer comprises a sequence selected from the group consisting of formulae IVa, IVb, IXa, IXb (SEQ ID NO 7 = IVa and SEQ ID No 8 = IVb; SEQ ID No 17 = IXa and SEQ ID No 18 = IXb).

Regarding claim 13, Matsumoto et al. teaches a primer composition comprising a pair of 18-24-mer oligonucleotide primers (SEQ ID NO 7 = IVa and SEQ ID No 8 = IVb) at least one of which <u>hybridizes</u> to an oligonucleotide sequence (SEQ ID No 17 = IXa and SEQ ID No 18 = IXb) selected from the group consisting of formulae IXa, IXb. (see page 1334 section RFLP analysis where composition containing primers are taught that are used for PCR)

Regarding claim 14, Matsumoto et al. teach the primer composition as claimed in claim 13, wherein at least one of said pair is a primer comprising a sequence <u>selected</u> from the group consisting of formulae IVa, IVb, IXa, IXb (see above).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the sequences of Matsumoto et al. to design the **primer** claimed in instant application as SEQ ID No 17 and 18 for detection of SEQ ID No 7 and SEQ ID No 8.

In the recent court decision KSR International Co. v. Teleflex Inc., 82 127 SCt 1727 (2007), the U.S. Supreme Court determined that if the combination of the claimed elements was "obvious to try" by a person of ordinary skill, this might show that such a

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combination was obvious under §103. Regarding "obvious to try", the Court stated:

"A person of ordinary skill is also a person of ordinary creativity, not an automaton. The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103."

The sequence of Pythium rDNA- interspecific region (ITS regions) are taught to one of ordinary skill by prior art. Matsumoto uses this sequence information to identify and classify the various Pythium species (see page 1339-phylogenetic analysis and one of ordinary skill in the art is capable of designing primer/probes useful for amplifying a given region of any nucleic acid whose sequence is known and detecting it using appropriate technique. PCR amplification is currently one of the fastest, cheapest way of detecting presence of any given nucleic acid, provided some information is available based on which amplification primers flanking the region to be amplified can be designed.

Since the claimed primers/probes simply represent structural homologs, which are derived from sequences suggested by the prior art as useful for primers of the Pythium interspecific region and concerning which a biochemist of ordinary skill would attempt to obtain suitable primers flanking the region of interest, the claimed primers are prima facie obvious over the cited references in the absence of secondary considerations.

expectation of success.

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Buck expressly provides evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18 mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that every primer would have a reasonable

8. Claims 11-12, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al. (2000). Mycol. Res. 104 (11):1333-1341 in view of Buck et al. (1999) Biotechniques 27: 528-536 further in view of Inoko et al. (WO 01/92572 A1 published June 12, 2001 with English equivalent document US 2003/0228585 A1 used for citing the exact lines and paragraphs).

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Regarding claims 11 and 12, Matsumoto et al. and Buck et al. teach 18- to 24mer oligonucleotide primer and composition (SEQ ID No 17 = IXa and SEQ ID No 18
=IXb) which hybridizes to an oligonucleotide sequence (SEQ ID NO 7 = IVa and SEQ ID
No 8 = IVb) selected from the group consisting of formulae IVa, IVb, IXa, IXb. (see
above as described in detail for claim 7).

Regarding claim 12, 17 and 22, Matsumoto et al. teach the primer (claim 12) or at least one primer (claim 17), at least one of said primer (claim 22) wherein said primer comprises a sequence selected from the group consisting of formulae IVa, IVb, IXa, IXb (SEQ ID NO 7 = IVa and SEQ ID No 8 = IVb; SEQ ID No 17 = IXa and SEQ ID No 18 = IXb).

Regarding claims 11 and 12, Matsumoto et al. and Buck et al. do not teach a substrate having immobilized thereon at least one oligonucleotide primer.

Regarding claims 11 and 12, Inoko et al. teach a substrate having immobilized thereon at least one oligonucleotide primer. (see page 6, par. 0102 where primers immobilized on substrate are taught. By this teaching Inoko et al. teach a substrate having immobilized thereon at least one oligonucleotide primer).

Regarding claims 17 and 22, Matsumoto et al. teach a method of detecting fungal infection of soil or vegetables by pathogenic Pythium species (see Matsumoto et al. page 1333 par. 1 and Table where pathogenic Pythium species from vegetables and soil are described. See page 1334 where RFLP analysis of r DNA-ITS, RAPD analysis based on PCR amplification is taught as method of detecting Pythium species).

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Regarding claims 17 and 22, Matsumoto et al. and Buck et al. do not teach packaging of primers in a kit format for use of Pythium detection.

Regarding claims 17 and 22, Inoko et al. teach primers for preparing a nucleic acid target can be included in a -----kit together with a substrate on which oligonucleotides are immobilized. (see page 6, par. 0102).

It would have been prima facie obvious to one of ordinary skill at the time the invention was made to package the primers of Matsumoto et al. and Buck et al. useful for detecting Pythium species in the kit format taught by Inoko et al. The motivation to do so is provided by Inoko et al. who state "A nucleic acid target for use in HLA typing is prepared by using the obtained DNA. The nucleic acid target can be prepared by amplifying a nucleic acid by using primers designed so as to correspond to a nucleotide sequence of capture oligo------Primers used for PCR are designed so that a nucleic acid target should include a complementary sequence of a capture oligo" (see page 6 par. 0097 to par. 0098). Thus explicitly providing motivation to one of ordinary skill to design primers immobilized on substrate. The target amplified by these primers have a sequence that is complementary to capture oligos (Note SEQ ID NO 17 and 18 are complementary to SEQ ID No 7 and 8 in the instant application) that are specific for Pythium species to be detected. Given this teaching of Inoko et al. one of ordinary skill recognizes the advantage of having the appropriate primers combinations and probes packaged in Kit format along with the instructions to use them.

Conclusion

9. Claims 7, 10-14, 17 and 22 drawn to primers and kit are rejected over prior art.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suchira Pande whose telephone number is 571-272-9052. The examiner can normally be reached on 8:30 am -5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suchira Pande Examiner Art Unit 1637

> 9 L. T.C. Holick, Ph.D. KENNETH R. HORLICK, PH.D PRIMARY EXAMINER

> > 1/7/08